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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/739,428	12/18/2000	Philip P.M. Finch	2537	3665

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UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
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EXAMINER	
ROANE, AARON F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/739,428	FINCH ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-25, 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharkey et al. (USPN 6,126,682).

Regarding claim 20, Sharkey et al. disclose a method for relieving pain associated with an intervertebral disc having a disc nucleus pulpous and an outer annulus fibrous

surrounding the nucleus pulpous, comprising; introducing a thermal transmitting element of a thermal probe (14) into the inner wall of annulus fibrosus of the intervertebral disc, which is interpreted broadly as the annulus fibrosus, the thermal probe defining proximal and distal ends and having a guidable region (flexible distal portion) adjacent the distal end thereof, the guidable region characterized by having sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus; and supplying thermal energy from a thermal energy source to the thermal transmitting element ("energy source" of col. 4, lines 28-32, "energy delivery element" of col. 5, lines 62-65 and (18) in col. 15) to heat the annulus fibrous adjacent the transmitting element sufficiently to relieve pain associated with the intervertebral disc, see abstract and col. 4 and figures 1D and 4.

Regarding claims 21 and 22, Sharkey et al. disclose the claimed invention, see col. 10-14 and element (16) of figure 4.

Regarding claims 23 and 24, Sharkey et al. disclose the claimed invention, see col. 4, lines 1-10 and figure 4.

Regarding claim 25, Sharkey et al. disclose the claimed invention, see col. 5, line 53 through col. 9, lines 37 and (12) in figure 4.

Regarding claims 29, 30, 35 and 36, Sharkey et al. disclose the claimed invention, see col. 15, lines 1-12 and col. 16, lines 49-67.

Regarding claims 31 and 32, Sharkey et al. disclose a method for relieving pain associated with an intervertebral disc, the intervertebral disc having a disc nucleus and all outer annulus surrounding the disc nucleus, the method comprising the steps of: accessing an intervertebral disc with a cannula; advancing a thermal probe having a heat transmitting region through the cannula into the inner wall of annulus fibrosus of the intervertebral disc, which is interpreted broadly as the annulus fibrosus, to position the heat transmitting region of the thermal probe in at least one of posterior, lateral and posterior-lateral areas of the annulus fibrous; and supplying thermal energy from a thermal energy source to the heat transmitting end region to heat the at least one area to treat pain associated with the intervertebral disc, wherein the step of accessing includes advancing a distal end of the cannula through the intervertebral disc to position the distal end within the annulus fibrous, see abstract and col. 4-14 and figures 1D and 4. It should be noted that the guidable region characterized by having sufficient rigidity to advance within the annulus fibrosus of the intervertebral disc in response to an axial force exerted on the proximal end of the thermal probe while having sufficient flexibility to substantially follow and conform to an azimuthal course defined by the natural striata of the annulus fibrosus, see figure 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-28, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (USPN 6,126,682) in view of Hertzmann et al. (USPN 5,084,043).

Regarding claims 26 and 33, Sharkey et al. disclose the claimed invention except for explicitly reciting that the cannula has an arcuate portion at the distal thereof. Hertzmann et al. disclose a method of treating spinal problems using an energy delivery means (132) and an arcuate or distally curved introducer/cannula "in situations where the patient's afflicted area is within the lumbar 5-sacrum 1 region of the vertebral column," see col. 7, lines 47-54 and figures 1 and 30B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Sharkey et al., as taught by Hertzmann et al., to use an arcuate or distally curved introducer/cannula "in situations where the patient's afflicted area is within the lumbar 5-sacrum 1 region of the vertebral column."

Regarding claims 27, 28 and 34, Sharkey et al. in view of Hertzmann et al. disclose the claimed invention.

Response to Arguments

Applicant's arguments filed 9/1/2005 and 7/25/2005 have been fully considered but they are not persuasive. The examiner will address each remark/argument in turn.

On page 8, Applicant summarizes the Sharkey et al. patent. Applicant quotes from Sharkey et al. and offers interpretations as to what specific recitations of Sharkey et al. could mean. Starting on 3, Applicant writes:

> *because "the distal portion 28 of intradiscal section 16 (of catheter 14) is desired to be incapable of piercing the annulus fibrosus 122 (col. 11, lines 21-22)," it can be appreciated that the catheter cannot enter, and especially cannot advance within, the annulus fibrosus upon exiting the introducer in the nucleus pulposus.*

Here, the examiner agrees, **but only to a degree**, although Sharkey et al. clearly states that the distal portion is incapable of piercing the annulus fibrosus, it is incorrect to assume the catheter cannot (i.e., in capable of) enter the annulus fibrosus and/or cannot (i.e., in capable of) advance within the annulus fibrosus in general. There is only support within Sharkey et al. to

state 1) the distal portion 28 of intradiscal section 16 (of catheter 14) is desired to be incapable of piercing the annulus fibrosus and 2) upon existing the introducer, wherein the exist orifice is within the nucleus pulposus, the distal portion 28 of intradiscal section 16 cannot enter, and especially cannot advance within, the annulus fibrosus. There is a slight distinction between the above statements.

Next, Applicant discusses the "inner wall of the annulus fibrosus" and explains that Sharkey et al. views this inner wall of the annulus fibrosus as a "transition zone between the annulus fibrosus and the nucleus pulposus." This is correct, but Sharkey et al. also states in col. 7, the last full paragraph:

> there is a transition zone between the annulus fibrosus and the nucleus pulposus made of both fibrous-like material and amorphous colloidal gel. The border between the annulus fibrosus and the nucleus pulposus becomes more difficult to distinguish as a patient ages, due to degenerative changes. This process may begin as early as 30 years of age. For purposes of this specification, the inner wall of the annulus fibrosus can include the young wall comprised primarily of fibrous material as well as the transition zone which includes both fibrous material and amorphous colloidal gels (hereafter collectively referred to as the "inner wall of the annulus fibrosus"). Functionally, that location at which there is an increase in resistance to catheter penetration and which is sufficient to cause bending of the distal portion of the catheter into a radius less than that of the

internal wall of the annulus fibrosus is considered to be the "inner wall of the annulus fibrosus".

So the inner wall of the annulus fibrosus can be broadly interpreted as part of the annulus fibrosus since both are comprised of a fibrous material. The examiner is well aware of the distinction between the mid to outer layers of the annulus fibrosus and the inner wall of the annulus fibrous. If Applicant wishes to distinguish between these two, Applicant should consider amending "annulus fibrosus" to – mid to outer layers of the annulus fibrosus--, --annulus fibrosus layers having no amorphous colloidal gel—or –annulus fibrosus layers having only fibrous material therein--. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See In re Self, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
September 12, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER